UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,492	06/23/2003	Robert John Mark	AM100012-P2	4877

25291 7590 02/17/2006

WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,492	MARK ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3 and 7 are drawn to a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:3 and SEQ ID NO:4, classified in class 536, subclass 24.5.

II. Claims 4 and 7 are drawn to a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:5 and SEQ ID NO:6, classified in class 536, subclass 24.5.

III. Claims 5 and 7 are drawn to a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:7 and SEQ ID NO:8, classified in class 536, subclass 24.5.

IV. Claims 6 and 7 are drawn to a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:9 and SEQ ID NO:10, classified in class 536, subclass 24.5.

V. Claim 8 (as dependent from claim 3) is drawn to a method for inhibiting apoptosis in a mammalian cell comprising administering a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:3 and SEQ ID NO:4, classified in class 536, subclass 24.5.

VI. Claim 8 (as dependent from claim 4) is drawn to a method for inhibiting apoptosis in a mammalian cell comprising administering a small interfering RNA molecule

having nucleotide sequence of SEQ ID NO:5 and SEQ ID NO:6, classified in class 536, subclass 24.5.

VII. Claim 8 (as dependent from claim 5) is drawn to a method for inhibiting apoptosis in a mammalian cell comprising administering a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:7 and SEQ ID NO:8, classified in class 536, subclass 24.5.

VIII. Claim 8 (as dependent from claim 6) is drawn to a method for inhibiting apoptosis in a mammalian cell comprising administering a small interfering RNA molecule having nucleotide sequence of SEQ ID NO:9 and SEQ ID NO:10, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because:

Inventions I-IV and V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups I-IV are directed to an siRNA molecule that inhibits cell apoptosis, while Groups V-VIII are directed to a method of inhibiting apoptosis admistering the siRNA molecule product to a mammalian cell. First, the siRNA product of Groups I-IV, as an anti-apoptotic molecule, can be used as a method for modulating cell proliferation, cell cycle progression, cell survival, or angiogenesis, for example. Alternatively, the anti-apoptotic siRNA molecule of Groups I-IV can be used in a materially different process such as a gene therapy

agent to treat or prevent apoptosis-induced diseases, i.e. Parkinson's disease. Second, inhibiting cell apoptosis can be achieved via administering anti-aptoptotic antibodies or antisense, which are materially different from siRNA. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the nucleotide sequences listed in claims 3-6 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434). In the instant application 1 sequence has been deemed to be a reasonable number.

Linked Inventions

Claims 1 and 2 link inventions I, II, III, and IV. Claim 8 links inventions V, VI, VII, and VIII. Claims 1 and 2 link inventions I-IV because the "molecule" recited in groups I-IV cannot be interpreted without claims 1 and 2, which specify the fundamental properties of the "molecule" of groups I-IV. Claim 8 link inventions V-VIII because the method of claim 8 depends from using the molecule of groups V-VIII.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, and 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will

be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana Shin
Examiner
Art Unit 1635

SEAN McGARRY
PRIMARY EXAMINER
1635